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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,413	04/24/2001	Francis P. Barry	640100-424	5476
7590 01/12/2006			EXAMINER	
Raymond J. Lillie, Esq. c/o Carella, Byrne, Bain, Gilfillan Cecchi, Stewart & Olstein 6 Becker Farm Road Roseland, NJ 07068			BARRETT, THOMAS C	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 01/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,413

Applicant(s)

BARRY ET AL.

Examiner

Thomas C. Barrett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION
REQUEST FOR CONTINUED EXAMINATION

The request filed on December 2, 2005 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/841,413 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Arguments

Applicant's arguments filed December 2, 2005 have been fully considered but they are not persuasive.

Response to Arguments

Applicant's arguments filed December 2, 2005 are very similar to the arguments filed August 4, 2004. They have been fully considered but they remain not persuasive.

The Applicant argues, "Abatangelo discloses a solid cell-matrix construct that contains mesenchymal stem cells." However, as noted previously, Abatangelo et al. does in fact disclose ***injecting*** a fluid cell biomatrix comprising a mesenchymal cell suspension. Abatangelo et al. states, "In addition, by varying the ratio of the components in said biodegradable matrices, the surgical handling properties of the cell biomatrix can be adjusted in a range from a dimensionally stable matrix, to a moldable putty-like consistency to a pliable gel or slurry, to a powder or to an injectable fluid." (col. 8, lines 20-29). Therefore, Abatangelo is not "directed solely to the implantation of a solid carrier." Abatangelo is directed to the repair of connective tissue defects. While the examples are only directed towards use of the solid carrier, this does not take away the

disclosure of the use of an injectable carrier. Abatangelo discloses, "Custom cell-matrix implants containing autologous, allogeneic, xenogeneic bone marrow and/or MSCs can be administered by using open surgical techniques, arthroscopic techniques or percutaneous injection." Therefore the injections are cited as alternatives to the use of the solid implant. Furthermore, the Applicant argues Abatangelo in view of Walsh, however this rejection is not made, and the arguments directed towards "teaching away" are not relevant.

The Applicant argues, "Abatangelo provides no evidence that the implantation of the esterified hyaluronic acid carrier containing mesenchymal stem cells resulted in meniscal repair." However, MPEP 2112.02 states, "when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated." Goldberg et al. and Abatangelo et al. ***perform the same method as the claimed present invention***, so therefore would inherently provide the same results, i.e. regeneration of meniscal tissue or prevention of osteophyte production. For example, if one takes an aspirin for a headache, it also happens to help prevent the possibility of blood clots. Even though aspirin has been used for decades to treat headaches, it has also been preventing strokes all these years. Therefore, the "result" of the "use" of aspirin for preventing strokes, is a "result" or "property" of aspirin's composition, and is not novel.

The added transitional phrase "consisting essentially of" fails to overcome the prior art. MPEP 2111.03 Transitional Phrases states: "If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting

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essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

And

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 28-30, 34-37, 41-44, 48-51, 55-58, 62, and 63-77 remains rejected under 35 U.S.C. 102(e) as being anticipated by Abatangelo et al. Abatangelo et al. discloses injecting a mesenchymal cell suspension with about a concentration of 1×10^7 cells per ml (col. 8, lines 20-37). The cells are within a sodium hyaluronate carrier (col.6, lines 52-59). The suspension can be used for meniscal repair (col. 14, lines 38-54).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 28, 31-33, 35, 38-40, 42, 45-47, 49, 52-54, 56 and 59-61 remains rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al. Goldberg et al. discloses regenerating meniscal tissue (p 4, line33- p 5, line 9) by injecting a suspension of mesenchymal stem cells into the joint space (p 6, lines 1-9).

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas C. Barrett whose telephone number is (571) 272-4746. The examiner can normally be reached Tuesday-Friday between 9:00 A.M. and 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Thomas Barrett', with a stylized flourish at the end.

Thomas Barrett
Examiner
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